IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

UNITED THERAPEUTICS CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	1:25CV368
	)	
LIQUIDIA TECHNOLOGIES, INC.,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

THOMAS D. SCHROEDER, United States District Judge.

This patent infringement case is before the court on the motion of Plaintiff United Therapeutics Corporation ("UTC") for a temporary restraining order ("TRO") and preliminary injunction. (Doc. 3.) Defendant Liquidia Technologies, Inc. ("Liquidia") has filed a response in opposition. (Doc. 34.) The court held a hearing on the motion on May 20, 2025, and the parties filed additional materials afterwards. (Docs. 44; 45; 46; 48.) For the reasons set forth below, the motion will be denied.

I. BACKGROUND

"UTC is a biotechnology company focused on the development and commercialization of products designed to address the needs of patients with chronic and life-threatening conditions." (Doc. 1 ¶ 3.) The company holds, among others, U.S. Patent No. 11,357,782 ("'782"), which was issued on June 14, 2022, and provides a method for treating lung disease. (Id. ¶¶ 1, 13–14.) This patent is the

subject of UTC's claims of infringement in this case. Pertinent here, the '782 patent claims the following:

> 1. A method of treating pulmonary hypertension comprising: providing an inhalation device for treating pulmonary hypertension in a human suffering from pulmonary hypertension comprising a powder formulation of treprostinil or a pharmaceutically acceptable salt thereof and a dry powder inhaler configured to administer single event dose of the powder formulation comprising treprostinil or a pharmaceutically acceptable salt thereof, wherein the single event dose comprises at least 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 3 breaths, wherein the dry powder inhaler is configured to administer the entire single event dose in less than 5 minutes with at least 5 micrograms of treprostinil or a pharmaceutically acceptable salt thereof being inhaled per breath through coordinated actuation of the dry powder inhaler with each breath, and administering to a human suffering from pulmonary hypertension with the dry powder inhaler the single event dose comprising at least 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof in 1 to 3 breaths, wherein the human administers the entire single event dose with the dry powder inhaler in less than 5 minutes by inhaling at least 5 micrograms of treprostinil or a pharmaceutically acceptable salt thereof per breath by coordinating one actuation of the dry powder inhaler for each separate breath, and wherein administration of an additional single event dose in the same manner occurs at least 3 hours later.

(Id. ¶ 16 (emphasis added).)

UTC "research[es] and develop[s] treatments for cardiovascular and pulmonary diseases," including pulmonary hypertension ("PH"). (Id. ¶¶ 3, 11.) PH "is a debilitating and often fatal disease characterized by elevated blood pressure in

the lungs." (Id. ¶ 11.) According to UTC, PH manifests in "different varieties," including pulmonary arterial hypertension ("PAH") and pulmonary hypertension associated with interstitial lung disease ("PH-ILD"). (Id.) PH-ILD "is a complex, progressive disease where a patient's PH is caused by interstitial lung disease," that is, "a broad set of disorders characterized by fibrosis or inflammation of the space between the lungs and pulmonary vasculature which is critical for gas exchange." (Id.)

As part of its efforts to treat PH and PH-ILD patients, UTC developed and sells Tyvaso and Tyvaso DPI. (Id. ¶ 2.) Tyvaso was approved by the United States Food and Drug Administration ("FDA") in 2009 and is administered to patients through a nebulizer, which is a device that aerosolizes a mist for inhalation. (Id. ¶ 2; Doc. 1-3 at 2.) Tyvaso DPI, which obtained FDA approval in 2022, "is the first marketed dry powder formulation of treprostinil in the United States." (Doc. 1 ¶ 2.) Tyvaso DPI is administered via a dry powder inhaler ("DPI"). (Doc. 5 ¶ 16.)

On August 19, 2024, Liquidia announced that it had obtained tentative FDA approval for Yutrepia, its own treatment for PAH and PH-ILD. (Doc. 1 ¶ 30.) Like Tyvaso DPI, Yutrepia is a "dry powder formulation of treprostinil" administered via a DPI. (Id. ¶ 2; Doc. 5 ¶ 16.) Although the FDA tentatively approved Yutrepia as a treatment for PH and PAH, it specified that final approval would not "be awarded until the expiration of UTC's 3-year regulatory

exclusivity for UTC's Tyvaso DPI on May 23, 2025." (Doc. 1 ¶ 30.) On May 23, 2025, Liquidia reported that the FDA granted final approval for Yutrepia. (Doc. 50.)

UTC alleges that "Liquidia engages or intends to imminently engage in the manufacture, use, offer for sale, sale, marketing, and/or distribution of Liquidia's Yutrepia (treprostinil) product and labeling prior to the expiration of the '782 patent." (Doc. 1 ¶ 39.) "Yutrepia . . . and its use in accordance with and as directed by Liquidia's Prescribing Information," UTC claims, "has [sic] and will continue to literally infringe, or infringe under the doctrine of equivalents, one or more claims of the '782 patent." (Id. ¶ 40.)

Although this case marks the first time UTC has asserted the '782 patent against Liquidia, it has asserted several other challenges to Yutrepia. After a 2022 bench trial, the United States District Court for the District of Delaware concluded that Yutrepia infringed UTC's U.S. Patent No. 10,716,793 ("'793"). United Therapeutics Corp. v. Liquidia Techs., Inc., 624 F. Supp. 3d 436, 473 (D. Del. 2022). The Federal Circuit affirmed. United Therapeutics Corp. v. Liquidia Techs., Inc., 74 F.4th 1360, 1363 (Fed. Cir. 2023), cert. denied, 144 S. Ct. 873 (mem.) (2024). In relevant part, the '793 patent claimed:

> 1. A method of treating pulmonary hypertension comprising administering by inhalation to a human suffering from pulmonary hypertension a

> therapeutically effective single event dose of a formulation comprising treprostinil or a pharmaceutically acceptable salt thereof with an inhalation device, wherein the therapeutically effective single event dose comprises from 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 3 breaths . . .
>
> 4. The method of claim 1, wherein the inhalation device is a dry powder inhaler . . .
>
> 6. The method of claim 1, wherein the formulation is a powder . . . .

(Doc. 34-12 at 27 (emphasis added).)

But in a parallel proceeding, the Patent Trial and Appeal Board ("PTAB") determined that the claims of UTC's '793 patent were unpatentable after inter partes review ("IPR"). Liquidia Techs., Inc. v. United Therapeutics Corp., No. IPR2021-00406, 2022 WL 2820717, at *18 (P.T.A.B. July 19, 2022). UTC appealed, and the Federal Circuit affirmed. United Therapeutics Corp. v. Liquidia Techs., Inc., No. 2023-1805, 2023 WL 8794633, at *1 (Fed. Cir. Dec. 20, 2023), cert. denied, 145 S. Ct. 352 (mem.) (2024). After the Federal Circuit confirmed that the '793 patent was invalid, the Delaware District Court vacated the conflicting portion of its earlier judgment pursuant to Federal Rule of Civil Procedure 60(b). United Therapeutics Corp. v. Liquidia Techs., Inc., No. 20-755, 2024 WL 1328902, at *3 (D. Del. Mar. 28, 2024).

When Liquidia amended the New Drug Application for Yutrepia to add a PH-ILD indication, UTC brought another patent infringement

lawsuit against Liquidia in 2023. (Doc. 34-2.) Originally, the lawsuit asserted that the additional indication infringed the '793 patent. (Id. at 1.) But after UTC obtained U.S. Patent No. 11,826,327 ("'327") in November 2023, it amended the complaint to assert an infringement claim pursuant to the '327 patent. (Doc. 34-7.) UTC's motion for a preliminary injunction in that case was denied. United Therapeutics Corp. v. Liquidia Techs., Inc., No. 23-975, 2024 WL 2805082, at *1 (D. Del. May 31, 2024) [hereinafter UTC, 2024 WL 2805082]. The case is scheduled for trial in June 2025.[1] (Docs. 4 at 13; 43 at 22.)

UTC filed the present action on May 9, 2025, and immediately requested that the court enter a TRO and preliminary injunction. (Docs. 1; 3.) Liquidia opposes injunctive relief. (Doc. 34.) The court heard argument on the motion on May 20, 2025, and the motion is ready for decision.

II. ANALYSIS

As UTC seeks a declaratory judgment that Liquidia will imminently infringe its '782 patent, the court has jurisdiction over the subject matter of this case pursuant to 28 U.S.C. §§ 1331

[1] Liquidia and UTC have also litigated against the FDA in the United States District Court for the District of Columbia, and Liquidia has this month sued UTC for infringement of Liquidia's patent, U.S. Patent No. 10,898,494 ("'494"), here in the Middle District of North Carolina. (Docs. 4 at 13; 4-11; 34 at 12.) On May 2, 2025, the United States District Court for the District of Columbia dismissed all remaining claims in the parties' suit against the FDA. (Doc. 4-10; Liquidia Techs., Inc. v. FDA, No. 24-2428, 2025 WL 1279359, at *14 (D.D.C. May 2, 2025).)

and 1338(a) as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

Federal Rule of Civil Procedure 65 governs the availability of a TRO and preliminary injunction to preserve the status quo pending trial. Hoechst Diafoil Co. v. Nan Ya Plastics Corp., 174 F.3d 411, 422 (4th Cir. 1999). The requirements for obtaining temporary and preliminary injunctive relief are the same. U.S. Dep't of Lab. v. Wolf Run Mining Co., 452 F.3d 275, 281 n.1 (4th Cir. 2006). Preliminary injunctions and TROs are extraordinary remedies that should only be granted "in [the] limited circumstances which clearly demand [them]." Direx Israel, Ltd. v. Breakthrough Med. Corp., 952 F.2d 802, 811 (4th Cir. 1991) (citations and internal quotation marks omitted). In order to obtain preliminary relief, a movant must establish (1) that it is likely to succeed on the merits of the dispute; (2) that it is "likely to suffer irreparable harm" in the absence of an injunction; (3) "that the balance of equities tips in [its] favor"; and (4) that injunctive relief is in the public interest. Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 20 (2008); Real Truth About Obama, Inc. v. Fed. Election Comm'n, 575 F.3d 342, 346–47 (4th Cir. 2009), vacated on other grounds, 559 U.S. 1089 (2010); Natera v. NeoGenomics Lab'ys., Inc., 106 F.4th 1369, 1375 (Fed. Cir. 2024) (citing Metalcraft of Mayville, Inc. v. Toro Co., 848 F.3d 1358, 1363 (Fed. Cir. 2017)). UTC must satisfy all four

requirements to receive relief. Real Truth, 575 F.3d at 346.

UTC's motion seeks a TRO and preliminary injunction. At the hearing on the motion, the court inquired whether the parties contended they needed to conduct any discovery prior to the court determining whether to enter a preliminary injunction. (Doc. 43 at 14.) In apparent acknowledgment that they "do know a lot about each other" due to their prior litigation history, both UTC and Liquidia agreed that the court can, and indeed should, decide the motion as one for a preliminary injunction at this time. (Id. at 14-15.)

A. Likelihood of Success on the Merits

Patent rights were deemed so essential to our republic that they were enshrined by our Founders in our Constitution. Article 1, Section 8, Clause 8 provides that "[t]he Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Once a patent is issued by the United States Patent and Trademark Office, it is presumed valid. 35 U.S.C. § 282; Proctor & Gamble Co. v. Teva Pharms. USA, Inc., 566 F.3d 989, 994 (Fed. Cir. 2009) (citing Kao Corp. v. Unilever U.S., Inc., 441 F.3d 963, 968 (Fed. Cir. 2006)).

To demonstrate likelihood of success on the merits in the context of a patent infringement case, the movant "must show that

it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent." Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1376 (Fed. Cir. 2009) (citing Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1364 (Fed. Cir. 1997)). "Absent an invalidity defense, 'the very existence of the patent with its concomitant presumption of validity satisfies the patentee's burden of showing a likelihood of success on the validity issue.'" BlephEx, LLC v. Myco Indus., Inc., 24 F.4th 1391, 1399 (Fed. Cir. 2022) (quoting Titan Tire, 566 F.3d at 1377)). However, "if the accused infringer presents a substantial question of validity, i.e., asserts an invalidity defense that the patentee cannot prove lacks substantial merit, the preliminary injunction should not issue." Id. (citation and internal quotation marks omitted); Altana Pharma AG v. Teva Pharms. USA, Inc., 566 F.3d 999, 1005–06 (Fed. Cir. 2009) (citing Entegris, Inc. v. Pall Corp., 490 F.3d 1340, 1351 (Fed. Cir. 2007)). This is because a patentee requesting preliminary injunctive relief "bears the burden of establishing a likelihood of success on the merits with respect to the patent's validity." Entegris, 490 F.3d at 1351 (citing Helifix, Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 1351 (Fed. Cir. 2000)). The burden of presenting a substantial question of invalidity at this stage is lower than what is required to prove invalidity at trial. Id.; see also Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1359 (Fed. Cir. 2001)

("Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial."); BlephEx, 24 F.4th at 1399 (noting that while invalidity at trial must be shown by clear and convincing evidence, a challenger "need only present evidence showing that there is a substantial question of validity despite the presumption of patent validity and [patentee's] arguments in favor of validity such that [patentee's] likelihood of success is in question" (citing Titan Tire, 566 F.3d at 1377–79)).

Put in practical terms, the Federal Circuit states that the ultimate burden remains on the patentee "to show that it is likely to succeed on the merits to obtain the extraordinary remedy of a preliminary injunction, including 'on the validity issue.'" BlephEx, 24 F.4th at 1399 (quoting Titan Tire, 566 F.3d at 1377)). To challenge validity, the initial burden rests on the alleged infringer "to produce some evidence to raise a substantial question of validity." Id. "To fulfill that burden," the alleged infringer "need only "assert[ ] a defense that [the patentee] cannot show 'lacks substantial merit.'" Id. (citing Genentech, 108 F.3d at 1364). The court then considers "'the evidence on both sides of the validity issue' to determine whether the alleged infringer has raised a substantial question of validity." Id. (citing Titan Tire, 566 F.3d at 1379).

UTC argues that Yutrepia infringes its '782 patent and that there is no substantial question regarding the patent's validity.

(Doc. 4 at 17–26.) In its briefing, it first asserts that "using Yutrepia according to its label and instructions for use will directly infringe claim 1" of the patent. (Id. at 20–22.) This is what is specifically alleged in its complaint. (Doc. 1 ¶¶ 46–47.) Second, it argues that Yutrepia use will also infringe claims 2 and 3 of the patent, which require "the administration of a third 'single event dose' at least 3 hours after the second 'single event dose' recited in claim 1" and "administration of the single event dose 'several times per day,'" respectively.[2] (Doc. 4 at 23.) Third, UTC contends that Yutrepia use will also infringe claim 8 of the patent, "which requires a single event dose in the method of claim 1 to provide 'a maximal treprostinil plasma concentration in the human of at least 0.65±0.28 ng/mL.'"[3] (Id.) Fourth, UTC

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[2] Claim 2 provides:

> 2. The method of claim 1, further comprising administering at least 3 hours later an additional single event dose comprising at least 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof in 1 to 3 breaths, wherein the human administers the entire single event dose with the inhalation device in less than 5 minutes by inhaling at least 5 micrograms of treprostinil or a pharmaceutically acceptable salt thereof per breath by coordinating one actuation of the dry powder inhaler for each separate breath.

Claim 3 provides:

> 3. The method of claim 1, wherein the human administers the single event dose several times per day.

(Doc. 1-1 at 27.)

[3] Claim 8 provides:

argues that Liquidia is intentionally inducing infringement of the '782 patent because Yutrepia's label "expressly directs physicians and patients to use the product in an infringing manner." (Id. at 25.) Finally, UTC contends there is no substantial question whether the '782 patent is valid because it was issued notwithstanding the patent examiner's awareness of the evidence of invalidity Liquidia presented to the PTAB during IPR of the '793 patent and enjoys a presumption of validity. (Id. at 25–26.)

Liquidia argues both that Yutrepia does not infringe the '782 patent and that the '782 patent is invalid. (Doc. 34 at 24–32.) Liquidia asserts that claim 1 of the '782 patent is limited to a method of treatment that is "inhaled per breath through coordinated actuation of the dry powder inhaler with each breath" and argues that the "plain terms" of the claim "require[] that two separate and distinct actions — actuation and inhalation — must be coordinated." (Id. at 25 (quoting Doc. 1-1 at 27).) Liquidia submits that "inhaled per breath" and "actuation" specify separate actions that must be "coordinated" to avoid rendering the terms surplusage. (Id. at 25–26.) Liquidia further contends that UTC's expert, Dr. Steven Nathan, "confirmed that there is no coordination

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> The method of claim 1, wherein the single event dose provides a maximal treprostinil plasma concentration in the human of at least 0.65±0.28 ng/ml.

(Doc. 1-1 at 28.)

required when using the Yutrepia device." (Id. (citing Doc. 6 ¶ 155).) Liquidia also cites both intrinsic and extrinsic evidence that it claims supports its preferred construction. (Id. at 26–29.) And because Liquidia argues UTC's evidence of direct infringement is lacking, it argues that its induced infringement argument must also fail. (Id. at 30.)

As for invalidity, Liquidia argues that the PTAB's invalidation of the '793 patent creates a substantial question of the '782 patent's validity. (Id. at 30–32.) Liquidia notes that even though Examiner Schmitt considered the same prior art as did the PTAB, his approval of the '782 patent is now contradicted by the PTAB's Final Written Decision determining invalidity on obviousness grounds issued only weeks later. (Id. at 30–31.) In allowing the '782 patent, Examiner Schmitt reasoned that it was not obvious because a person of ordinary skill in the art would be unable to "predict the dose, the number of breaths, and the timing of taking the drug" based on the relevant prior art. (Id. at 30 (citing Doc. 34-15 at 48).) Liquidia argues that in rejecting the '793 patent, the PTAB reached directly contrary conclusions, expressly determining that UTC's claimed dose — 15 to 90 micrograms of treprostinil — and its delivery over the course of "1 to 3 breaths" were obvious from the prior art. (Id. at 31.) Liquidia contends that if the PTAB's Final Written Decision invalidating the '793 patent had been available to Examiner Schmitt prior to

the issuance of the '782 patent, he would not have issued the '782 patent. (Id. at 31–32.) This conclusion is inescapable, it argues, because during UTC's prosecution of Patent Application No. 17/745,333 ("'333"), which is in the same family as the '782 patent, Examiner Schmitt relied on the PTAB's Final Written Decision in the '793 IPR to conclude that claims similar to those of the '782 patent are non-patentable because they are obvious. (Id. at 27, 31.)

UTC responds that the claim of the '782 patent that the second administration of a single event dose should occur "at least three hours later" was not undermined by the '793 patent IPR. (Docs. 43 at 69; 4 at 14.) That is because, it argues, the PTAB did not reach the claim in the '793 patent as to the "at least 3 hours later" limitation, and Examiner Schmitt's allowance of the '782 patent did. (Doc. 43 at 26–28, 68–69.) Liquidia counters that, on May 12, 2025, days after UTC's present lawsuit was filed, Examiner Schmitt rejected UTC's argument during prosecution of UTC's application for the '333 patent, explicitly concluding that the three-hour interval is obvious. (Doc. 43 at 69–73.)

UTC's position as to the validity of the '782 patent rests on the patent's initial presumption of validity due to its issuance and this principal contention: "[n]othing about the '793 IPR disrupts the presumption of validity that each claim of the '782 patent enjoys" because Examiner Schmitt considered the same prior

art that was considered in the '793 IPR. (Docs. 4 at 26; 43 at 24-26.) As set forth below, however, Liquidia's evidence makes a persuasive showing that subsequent decisions by patent officials seriously undermine UTC's position.

As it now contends, UTC claimed before Examiner Schmitt during prosecution of the '782 patent that three elements of the claims render the '782 patent non-obvious: (1) the dosage; (2) the number of breaths; and (3) the minimum three hour spacing between doses. (Docs. 4 at 14; 4-15 at 47.) A claim is patentable if "the differences between it and the prior art" are such "that a relevant artisan at the priority date would not have found the claimed subject matter as a whole obvious." Yita LLC v. MacNeil IP LLC, 69 F.4th 1356, 1363 (Fed. Cir. 2023) (citing 35 U.S.C. § 103(a)). At the same time UTC was prosecuting the '782 patent before Examiner Schmitt, Liquidia was challenging the validity of UTC's '793 patent through IPR. The PTAB initially determined that there was a question as to obviousness based on prior art - namely: U.S. Patent No. 6,521,212 ('212); an abstract the Federal Circuit dubbed "JESC"[4]; and an abstract the Federal Circuit dubbed "JAHA".[5]

[4] Robert Voswinckel et al., Inhaled treprostinil is a potent pulmonary vasodilator in severe pulmonary hypertension, 25 European Heart J. 22 (2004).

[5] Robert Voswinckel et al., Inhaled Treprostinil Sodium (TRE) For the Treatment of Pulmonary Hypertension, in Abstracts from the 2004 Scientific Sessions of the American Heart Association, 110 Circulation III-295 (Oct. 26, 2004).

(Doc. 43 at 66-67.) Simultaneously, UTC provided the same prior art to Examiner Schmitt. (Id.) Examiner Schmitt considered the prior art and accepted UTC's arguments that the methods claimed by the '782 patent were not obvious. (Doc. 4-15 at 49.) In an April 2022 decision, he described the claimed method as follows:

> [D]osing a dry powder, in at least 15 micrograms to 90 micrograms of treprostinil, delivered in 1 to 3 breaths, with at least 5 micrograms of Treprostinil being inhaled per breath, wherein the administration of an additional single event dose in the same manner occurs at least 3 hours later . . .

(Doc. 4-15 at 48.) He reasoned that a person of ordinary skill in the art could not predict "the dose, the number of breaths, and the timing of taking the drug" based on the relevant prior art. (Id.) He thus allowed the claims. (Id.)

But two months after Examiner Schmitt's decision, the PTAB issued its July 19, 2022 Final Written Decision, reaching the opposite conclusion with respect to the dosage and number of breaths associated with the method of the '793 patent based on the same evidence. (Doc. 34-16 at 17–18, 31–33.) Contrary to Examiner Schmitt, the PTAB concluded that "the prior art taught or suggested a therapeutically effective single event dose comprising from 15 micrograms to 90 micrograms of treprostinil" and that "JAHA teaches or suggests" limitation of delivery to 1 to 3 breaths. Liquidia Techs., Inc. v. United Therapeutics Corp., No. IPR2021-00406, 2022 WL 2820717, at *6–7 (P.T.A.B. July 19, 2022). The PTAB thus

invalidated the '793 patent, the Federal Circuit affirmed, and the Supreme Court denied certiorari. United Therapeutics Corp. v. Liquidia Techs., Inc., No. 2023-1805, 2023 WL 8794633, at *1 (Fed. Cir. Dec. 20, 2023), cert. denied, 145 S. Ct. 352 (mem.) (2024). This determination that the dosage and quantity of breaths claimed by the '793 patent were obvious and not patentable casts substantial doubt on Examiner Schmitt's prior conclusion that seemingly identical claims in the '782 patent are not obvious.

At oral argument, UTC emphasized that the PTAB's decision invalidating the '793 patent did not undermine Examiner Schmitt's other conclusion - that the '782 patent's claimed method that "administration of [an] additional single event dose . . . [should] occur[] at least 3 hours later" - was not obvious from the prior art. (Doc. 43 at 69 (emphasis added).) To that extent, that appears true. Yet Liquidia has provided substantial evidence that a three-hour interval between an initial and subsequent event dose of treprostinil, as claimed in the '782 patent, is obvious from prior art. (See Docs. 34-38 at 12–14; 34-39 at 10–13; 34-40 at 2–3; 34-41 at 8).

Most notably, Liquidia points to Examiner Schmitt's May 12, 2025 rejection of UTC's attempt to obtain approval of its '333 patent, which makes similar claims.[6] There, the examiner expressly

[6] The '333 patent application claims in relevant part:

acknowledged the PTAB's invalidation of the '793 patent. (Doc. 34-41 at 8 (rejecting UTC's argument that "the dosage, number of breaths, time period, and time between dosing [are] not obvious" on the grounds that "the PTAB has determined that the dosage, number of breaths, and time period [are] obvious based on the same references" in the '793 patent IPR).) And although acknowledging that the PTAB's decision regarding the '793 patent did not address the 3-hour window between doses, Examiner Schmitt nevertheless concluded that a person of ordinary skill in the art would have found that the interval "is obvious as one would continue to treat a patient in need of treatment after the initial dose wore off. This is routine." Id. Moreover, Examiner Schmitt rested this conclusion on the same prior art that he previously relied on to

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> 1. A pharmaceutical product comprising a formulation comprising treprostinil or a pharmaceutically acceptable salt thereof and an inhalation device configured to administer a single event dose of the formulation to a human comprising at least 15 micrograms of treprostinil or a pharmaceutically acceptable salt thereof that is delivered with 1 to 3 breaths, wherein the inhalation device is further configured to administer the entire single event dose in less than 5 minutes with at least 5 micrograms of treprostinil or a pharmaceutically acceptable salt thereof being inhaled per breath through an actuation of the inhalation device coordinated with each breath.
>
> 2. The product of claim 1, wherein the inhalation device is further configured to administer each single event dose at least 3 hours apart from a prior single event dose.

(Doc. 34-33 at 3.)

determine that the '782 patent was valid and which the PTAB and Federal Circuit concluded rendered the '793 patent obvious: the '212 patent; JESC; and JAHA.[7] (Doc. 34-41 at 4.) This all supports Liquidia's argument that if Examiner Schmitt were considering whether to issue the '782 patent anew with the benefit of the '793 patent IPR, he would likely deem the patent invalid as obvious.

To be sure, as UTC pointed out at oral argument, the '333 patent and '782 patent make different claims. The '333 patent claims a pharmaceutical product, and the '782 patent claims a method of treatment. (Doc. 43 at 28.) If it is not the case that what constitutes an obvious inference from the prior art with respect to a pharmaceutical product is obvious as to a method of treatment, UTC has not persuasively made that case. Indeed, as Liquidia pointed out at the hearing, in prosecuting its '333 patent before Examiner Schmitt, UTC appears to have distinguished the '793 patent on grounds other than the 3-hour interval between doses

[7] Examiner Schmitt concluded:

> To address the **3 hours later** time point, the JESC reference shows efficacy max at 50 minutes and 1/2 max at 110 minutes. Therefore the duration would wane over the next period of time, which one estimate going from 1/2 max to zero would take time. Also JSEC [sic] measured time points out to 180 minutes (3 hours) and noted a "long lasting" effect. As such one would note the duration is "long lasting" and measured to 180 minutes, thereby creating a starting point to optimize continues treatment. Therefore this argument is not persuasive.

(Doc. 34-38 at 12-13.)

limitation.[8] (Doc. 34-33 at 4-6.) And because UTC rests its argument in favor of the '782 patent's validity on precisely the same prior art that the PTAB and Examiner Schmitt found shows that materially-similar claims in the '793 patent (and it appears the '333 patent) are not patentable, there is at least a substantial question as to the validity of the '782 patent that UTC has yet to persuasively counter.

The final element of Claim 1 that UTC presses to support imposing injunctive relief is that the dose of treprostinil be "inhaled per breath through coordinated actuation of the dry powder inhaler with each breath." (Doc. 1 ¶ 16.) The parties note that this claim element has not been construed previously. (Doc. 43 at 76.) Liquidia argues both that Yutrepia does not infringe this element, and that it is nevertheless obvious. (Doc. 34 at 32.) UTC argues that Yutrepia infringes because the commercially available DPI devices at the time of the patent were "all breath powered, breath actuated" and that to accept Liquidia's argument would read every existing DPI at the time of the patent out of the

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[8] UTC identified these distinctions in the claims of the '333 patent:

> (a) "configured to administer the entire single event dose in less than 5 minutes" (claim 1); and
>
> (b) "at least 5 micrograms of treprostinil or a pharmaceutically acceptable salt thereof being inhaled per breath through an actuation of the inhalation device coordinated with each breath" (claim 1) (emphasis added).

(Doc. 34-33 at 5-6.)

scope of the claim. (Doc. 43 at 19.)

Coincidentally, both parties cite the same source – an article by Paul J. Adkins, Ph.D. entitled, "Dry Powder Inhalers: An Overview," published October 2005 in the journal Respiratory Care. Liquidia points out that in that article the author states that "DPIs obviate coordination or actuation and inspiration (a limitation of MDIs [metered-dose inhalers]) because DPIs are essentially breath-activated." (Doc. 34-6 at 3.) Dr. Adkins also observes that all commercially available DPIs are "passive," meaning that the user must inhale to receive the dose of medication, which may be hard for users who are asthmatic, and that companies were investigating ways to provide energy to the devices. (Id.) Based on this, Liquidia argues, breath actuated DPIs were known by at least 2005 and were obvious. (Doc. 34 at 32.) Liquidia also points to Examiner Schmitt's decision in connection with another UTC patent (which was prior art to the '793 patent) where he concluded that a reference to an "inhaler" would be understood by a person of ordinary skill in the art to be "a dry powder inhaler" and that "[s]uch dry powder inhalers were well known and 'widely accepted' as of 2006." (Doc. 42-1 at 9-10.) Based on this showing, Liquidia has thus carried its burden of calling this ground for validity of the '782 patent into doubt too, and UTC has not provided sufficient evidence or argument that suggests Liquidia's arguments lack substantial merit. At this

stage, the teachings of Atkins regarding DPIs and Examiner Schmitt's rejection of UTC's efforts to validate patents on this ground create a substantial question of the validity of the '782 patent.

Infringement, of course, depends on a valid patent. Commil USA, LLC v. Cisco Sys., Inc., 575 U.S. 632, 644 (2015). Because the court finds there is a substantial question as to the validity of the '782 patent, it concludes that UTC has not shown that it is likely to prevail on the merits of its claim. Entegris, 490 F.3d at 1351 (observing that where there is a substantial question regarding invalidity, equitable relief should not issue); see also Amazon.com, 239 F.3d at 1359–60 (alleged infringer created a "serious challenge to the validity of [patentee's] patent" at the preliminary injunction phase where "asserted prior art" taught the "key limitations" of the patent at issue, even though the district court concluded the prior art did not "recite each and every limitation of the claims") (emphasis added); Helifix, 208 F.3d at 1351–52 (alleged infringer raised a "substantial question of patent invalidity" at the preliminary injunction phase even where whether the prior art disclosed three elements of claim 1 of the challenged patent remained "a very open question").[9] The court

[9] The parties concentrated the bulk of their arguments as to validity on claim 1. As Liquidia also argued, however, the court finds that Liquidia has raised substantial questions regarding the validity of claims 2, 3, and 8 of the '782 patent, which UTC asserts in its brief.

thus need not reach the parties' contentions on infringement at this stage.

For these reasons, Liquidia's showing of a substantial question as to the validity of UTC's '782 patent and thus the merits of UTC's infringement claim causes this factor to weigh against issuance of injunctive relief. See Titan Tire, 566 F.3d at 1377–80; BlephEx, 24 F.4th at 1399. In fact, "[a] preliminary injunction should not issue if an alleged infringer raises a substantial question regarding either infringement or validity, i.e., the alleged infringer asserts an infringement or invalidity defense that the patentee has not shown lacks substantial merit." AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1050 (Fed. Cir. 2010) (citing Genentech, 108 F.3d at 1364)). Accord Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., 357 F.3d 1319, 1325 (Fed. Cir. 2004) (noting that "a movant is not entitled to a preliminary injunction if he fails to demonstrate likelihood of success on the merits").

Although the court's conclusion that UTC is not likely to

Liquidia points out that the claims of the '782 patent "nearly complete[ly] overlap" with those of the invalid '793 patent and the "rejected claims of the '333 application" and contends that there are no "patentable differences between the claims" of these three patents. (Doc. 34 at 32.) UTC did not respond to this argument as to these claims, either in a brief or at the hearing, and has not shown that Liquidia's arguments of invalidity as to these claims of the patent lack substantial merit or that any limitations of these claims render them patentable irrespective of the question of the validity of claim 1. BlephEx, 24 F.4th at 1399.

succeed on the merits of its claim alone sufficiently warrants denial of its motion for a preliminary injunction, the court's consideration of the remaining preliminary injunction factors confirms that conclusion.

B. Irreparable Harm

A party seeking preliminary injunctive relief must also demonstrate that it will suffer irreparable harm if its request is not granted "and establish a causal nexus between the alleged infringement and the alleged harm." Natera, 814 F.3d at 1378. "[T]he irreparable harm inquiry seeks to measure harms that no damages payment, however great, could address." Celsis In Vitro, Inc. v. CellzDirect, Inc., 664 F.3d 922, 930 (Fed. Cir. 2012) (citing Altana Pharma, 566 F.3d at 1010). Irreparable harm may manifest as harms that are difficult to quantify or impossible to redress, and "the mere possibility of future monetary damages does not defeat a motion for preliminary injunction." Id. (citing Abbott Lab'ys. v. Sandoz, Inc., 544 F.3d 1341, 1362 (Fed. Cir. 2008)). "[E]vidence that a patent owner unduly delays in bringing suit against an alleged infringer negates the idea of irreparability." Pfizer, Inc. v. Teva Pharms., USA, Inc., 429 F.3d 1364, 1382 (Fed. Cir. 2005) (citing Polymer Techs., Inc. v. Bridwell, 103 F.3d 970, 974 (Fed. Cir. 1996)).

UTC argues that it will suffer irreparable harm principally in the form of price erosion, reduced sales and market share, and

lost goodwill and marred reputation. (Doc. 4 at 26–31.) It also contends that "even if some of [its] damages were quantifiable, Liquidia would likely be unable to pay [its] potential monetary damages." (Id. at 30 (citing Doc. 5 ¶¶ 153–58).) Finally, it argues that there is a sufficient nexus between the harms alleged and Liquidia's allegedly infringing acts. (Id. at 31.)

Liquidia responds that UTC has delayed in asserting the '782 patent, which it contends "shows the lack of irreparable harm." (Doc. 34 at 15.) It observes that UTC obtained the '782 patent in June 2022, but waited until May 9, 2025, to assert it against Liquidia. (Id.) Liquidia further points out that UTC's infringement allegation stems from a November 2024 Yutrepia label and that "UTC has not explained why it waited another six months" to assert the '782 patent. (Id. at 15 n.4.) Liquidia also contends that UTC is "precluded" from relitigating irreparable harm because the contention was rejected when the District of Delaware District Court denied a preliminary injunction as to UTC's '327 patent. (Id. at 16.) Liquidia characterizes UTC's asserted injuries as speculative, unquantified, and lacking in the required nexus between the claimed harm and purported infringement. (Id. at 17–22.) Finally, Liquidia argues that it is financially viable to compensate UTC for "any monetary losses" after Yutrepia launches. (Id. at 22.)

As to delay, UTC responds that it lacked a Hatch-Waxman claim

as to the '782 patent and thus Hatch-Waxman jurisdiction was lacking. This is so, it argues, because Yutrepia is based on Tyvaso, whereas the '782 patent claims a method involving DPI and can only be listed as a patent associated with Tyvaso DPI. (Doc. 43 at 6–7.) So, UTC argues, it could only bring Hatch-Waxman claims against Liquidia for patents UTC listed in the Orange Book[10] related to Tyvaso. (Id. at 7–10.) Consequently, UTC says, it was required to bring any action with respect to the '782 patent pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. (Id. at 10.) And because Declaratory Judgment Act claims are not ripe until the launch of an infringing product is "imminent," UTC argues, it waited until its claims against the FDA were dismissed ("a week to the day before we filed this suit"), which was two weeks before its regulatory exclusivity period was scheduled to elapse, before filing suit. (Doc. 43 at 10-11.)

As a threshold matter, the court is not persuaded by Liquidia's argument that the denial of a preliminary injunction in the Delaware litigation "precludes" UTC from arguing irreparable harm in this case. Most obviously, UTC's arguments before this court rest in part on evidence that the Delaware court did not consider, including the deposition of a UTC executive that occurred

[10] The Orange Book is the colloquial name for "an FDA publication that includes all patent information that companies have submitted to the agency" related to "existing brand-name drugs." Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 880 (D.C. Cir. 2004).

in November 2024 — nearly six months after the Delaware court denied UTC's request. (Doc. 8-19.)

Even if UTC could not have previously brought a Hatch-Waxman lawsuit against Liquidia as to the '782 patent, it is not clear why, in light of the fact that UTC previously raised other patent infringement claims against Liquidia involving Tyvaso DPI, UTC waited until two weeks before final FDA approval to bring the present case. While declaratory judgment actions for alleged infringement are typically brought by the alleged infringer, suits by the patentee have been recognized. See Lang v. Pac. Marine & Supply Co., 895 F.2d 761, 763 (Fed. Cir. 1990) ("If the controversy requirement is met by a sufficient allegation of immediacy and reality, we see no reason why a patentee should be unable to seek a declaration of infringement against a future infringer when a future infringer is able to maintain a declaratory judgment action for noninfringement under the same circumstances."); see also Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1570-71 (Fed. Cir. 1997) (finding no abuse of discretion in the district court's hearing of a patentee's claims for declaratory judgment where the patentee alleged that the infringer, who had yet to receive FDA approval for its ANDA, communicated that it intended to market its product in six months, before the patent's expiration, and the

patentee had a reasonable apprehension of irreparable harm).[11]

No doubt that immediacy has been shown in the present case, but it likely could have been asserted before now. Liquidia submitted its amended NDA to FDA to note a PH-ILD indication on July 27, 2023. (Doc. 37 Table 3.) UTC sued on the '793 patent on September 5, 2023, and when its '327 patent issued in November 2023, UTC amended its complaint two days later to add the '327 patent. (Id.) UTC claimed imminent harm in February 2024 when it sought a preliminary injunction in the Delaware District Court against Yutrepia for the treatment of PH-ILD, as UTC's regulatory exclusivity was then set to expire March 31, 2024, and Liquidia had broadcast its intention to launch the product for both PH and

[11] In Glaxo, the Federal Circuit observed that although the Hatch-Waxman Act "provides the federal courts with jurisdiction to hear infringement cases regarding claims directed to drugs or to methods of using drugs, it does not provide jurisdiction to hear infringement cases regarding claims directed to methods for making drugs." Id. at 1570 (citing 35 U.S.C. § 271(e)(2) (1994)). However, the court concluded, the patentee could bring claims for infringement of its method patent that was not listed in the Orange Book pursuant to the Declaratory Judgment Act alongside the claims for which the Hatch-Waxman Act provided jurisdiction because the alleged infringer had communicated to the patentee that it intended to market its product "pursuant to FDA approval" prior to the expiration of its method patent. Id. These allegations of "imminent FDA approval and actual threats of future infringement, the court said, "create[d] an actual case or controversy" that the district court could consider pursuant to the Declaratory Judgment Act. Id. at 1571. To be sure, Glaxo and Lang were decided under the Federal Circuit's "reasonable apprehension of suit" standard, which the Supreme Court rejected in MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007) (considering "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment").

PH-ILD indications. (Doc. 34-9 at 7, 10.) Because the '782 patent issued in June 2022, UTC would have been aware of any potential infringement claim by then.[12] (Doc. 1-1.) If UTC believed that harm was not sufficiently imminent in March 2024, it was nearer at hand in August 2024, when Liquidia announced that Yutrepia had been granted tentative FDA approval for PAH and PH-ILD indications. (Doc. 1 ¶ 30.) UTC's claimed harms became even closer on November 26, 2024, when Liquidia filed its proposed label for Yutrepia (and accompanying instructions) that UTC cites as a basis for its claim of infringement in its current complaint. (Doc. 1 ¶¶ 20-29). UTC has not reconciled its earlier litigation contention that irreparable harm was sufficiently "imminent" in February 2024 regarding the '327 patent with its current argument that '782 harm only became sufficiently imminent two weeks before its regulatory exclusivity was scheduled to lapse. In any event, while UTC's

[12] Reckitt Benckiser Pharmaceuticals, Inc. v. Biodelivery Sciences International, Inc., No. 5:13-CV-760, 2014 WL 2119822, (E.D.N.C. May 20, 2014) (unpublished), relied on by UTC, is distinguishable. There, the court observed that although the defendant had announced its intent to market a purportedly infringing drug "once it obtains FDA approval," the court had not received any evidence that FDA had acted on the alleged infringer's NDA. Id. at *2. Because "any actual future alleged infringement of [the] patent" depended on the future "contingent events" of the FDA approving the alleged infringer's NDA and the alleged infringer's decision to market its drug pursuant to the NDA, the court concluded that the plaintiff's claim for declaratory judgment was premature. Id. Eisai v, Ltd. v. Mutual Pharmaceutical Co., Inc., No. 06-3613, 2007 WL 4556958, (D.N.J. 2007), cited by UTC, is also distinguishable in part, as the parties stipulated that the alleged infringer would give the patentee 45 days' written notice before "market[ing], offer[ing] to sell or sell[ing]" a generic product under its ANDA. Id. at *7.

last-minute filing in the present case, as compared to its earlier litigation efforts, is not entirely consistent with its claims of harm, the court need not rely on this argument by Liquidia, as other grounds indicate that UTC has failed to demonstrate that an injunction should issue.[13]

As to UTC's other arguments, "price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm." Celsis, 664 F.3d at 931 (citing Abbott Lab'ys. 544 F.3d 1341 at 1362). Price erosion can be irreparable because of the difficulty of reversal. Id. at 930. Loss of market share "constitutes irreparable injury because market share is so difficult to recover." Henkel Corp. v. Coral, Inc., 754 F. Supp. 1280, 1322 (N.D. Ill. 1990) (citation and internal quotation marks omitted), aff'd, 945 F.2d 416 (Fed. Cir. 1991).

UTC proffered evidence that it may suffer price erosion as a result of Yutrepia's launch. (Docs. 8 at 27–28; 8-19 at 26:6-27:3, 79:6-18; 138:16-141:22.) UTC contends, and its expert, Dr. Selck, opines, that if Yutrepia launches, "payors will demand that

[13] Even assuming that UTC could only have listed the '782 patent for Tyvaso DPI, it remains unclear why it did not do so until April 24, 2025, just days before UTC filed the present lawsuit. (Doc. 34-37.) As Liquidia's evidence shows, UTC's Tyvaso DPI Orange Book listing contains eight patents: five submitted June 17, 2022, one submitted August 15, 2023, one submitted November 28, 2023, and the '782 patent submitted April 24, 2025. (Id.) As Liquidia argues, UTC certainly knew when its '782 patent was approved on June 14, 2022, that it could be listed for Tyvaso DPI, as UTC listed five patents just three days later.

UTC lower its prices." (Docs. 8 at 27-28; 5 ¶ 78.) Dr. Selck reports that in comparable pharmaceutical markets, similar entry resulted in "price erosion of up to 30% to 40% or more." (Doc. 5 ¶ 68.) Based on this evidence (including the precise figures UTC filed under seal), it is probable that if Yutrepia launches, UTC will see some erosion in its prices.

Liquidia has provided evidence to question at least the extent, if not the existence, of any price erosion. Although UTC has argued in other litigation that Yutrepia's imminent entry will erode prices, UTC has repeatedly raised its prices annually. (Doc. 34 at 9.) In fact, it raised prices on Tyvaso DPI in 2025, although Yutrepia was scheduled for final FDA approval in May 2025. (Doc. 34-22 at 7.) More to the point, the report of Liquidia's expert, Douglas Kidder, opines that, based on his review of UTC's projections for the next decade, UTC forecasts significant continued increases in prices. (Doc. 37 at 30-33.) Nevertheless, while third party payors generally negotiate and set prices annually (meaning they would have been set for 2025), UTC has provided some evidence that third party payors may seek formulary and pricing changes outside of the regular schedule if Yutrepia goes to market. (Docs. 43 at 55–58; 8 at 29.) In sum, the court concludes that some price erosion is likely, but the extent of it appears speculative.

UTC's claim that it will lose profits and sales is similarly

mixed. Dr. Selck submits that if Yutrepia enters the market, "some payors will attempt to negotiate exclusive status or favorable placement for either Yutrepia or Tyvaso" and that Liquidia will endeavor to obtain exclusive arrangements for Yutrepia. (Doc. 5 ¶ 91.) If Liquidia succeeds, Dr. Selck opines, Yutrepia "would be the only treatment covered by that insurer, and hence the vast majority (if not all) of the patients . . . covered by that insurer would switch to Yutrepia." (Id.) Moreover, Dr. Selck predicts that Tyvaso products and Yutrepia will "directly compete" and that "Liquidia is positioning Yutrepia as an alternative to the Tyvaso products." (Id. ¶ 93.) All told, UTC contends that if Yutrepia comes to market, at least some sales that otherwise would have gone to UTC will instead go to Liquidia. (Docs. 4 at 28–30; 5 ¶¶ 91–97.)

As the District Court in Delaware pointed out, "[l]ost sales standing alone are insufficient to prove irreparable harm; if they were, irreparable harm would be found in every case involving a 'manufacturer/patentee, regardless of circumstances.'" UTC, 2024 WL 2805082, at *11 (citing Automated Merch. Sys., Inc. v. Crane Co., 357 F. App'x 297, 300–01 (Fed. Cir. 2009)). And although UTC argues that Liquidia will take some of its patient sales, Liquidia has provided evidence, based on UTC's own projections, that UTC contemplates consistent increased sales and prices through 2035. (Doc. 37 at 31, 32.)

UTC's claim of lost market share is more persuasive. But the undisputed record indicates that there are thousands of PH and PH-ILD patients who remain untreated. (Doc. 37 ¶ 87.) The Delaware District Court noted the same in discounting this claimed harm. UTC, 2024 WL 2805082, at *11 (concluding that even if UTC and Liquidia both sold their products, some patients would nevertheless remain untreated). Even under UTC's own projections, UTC treats a small fraction of the growing population of PH patients and less than 25% of PH-ILD patients, and it will not treat 50% of PH-ILD patients until early next decade. (Doc. 34 at 24 (citing UTC, 2024 WL 2805082, at *11).)[14] In a market where increasing numbers of patients are being diagnosed with the relevant illness and UTC is not projected to provide treatment for them, a claim of lost market share loses some force. Dr. Selck opines that Yutrepia sales will come at the expense of Tyvaso sales. (Doc. 5 ¶¶ 91, 93–96.) But he cannot say why patients would prefer one over the other, as he says physicians make the prescribing decision. (Id. ¶ 91.) All told, the court concludes that UTC may lose a portion of its market share if Yutrepia proceeds to market. While this weighs in UTC's favor, the extent to which UTC's market share may decrease is uncertain and there is

[14] UTC's current projections, submitted under seal in this case, are not substantially different from those acknowledged by the Delaware District Court. (See Doc. 9 37 ¶¶ 97-104; Doc. 37 ¶ 70.)

persuasive evidence that UTC is not presently meeting market demand for PH and PH-ILD treatments and will not do so in the future – long past the life of the '782 patent. Moreover, as noted below, both parties argue that Yutrepia is not a generic for Tyvaso and their products are not necessarily interchangeable.

UTC's allegation that it will suffer reputational harm is its weakest. Dr. Selck submits that absent relief from the court, "Yutrepia may be allowed to enter the market and then be forced to withdraw." (Doc. 5 ¶ 114.) If this occurs, Dr. Selck opines that "external stakeholders" might "view [UTC] negatively for having caused removal of an additional product for PAH and PH-ILD patients from the marketplace." (Id.) And worse yet, "negative views likely would be compounded if, following such removal, [UTC] attempted to restore prices to the levels prior to Yutrepia entry." (Id.) It is hard to see how this view differs substantially from UTC's current efforts to keep Yutrepia off the market. Thus, the court is not convinced that the public would look more favorably on UTC's efforts to prohibit Yutrepia through a pretrial injunction than it would if the product were later found to be infringing. UTC's fear of reputational injury accordingly appears speculative. Accord UTC, 2024 WL 2805082, *12.

The evidence that most undermines UTC's claims of irreparable harm, however, is the public statements of its executives. UTC's own management has publicly advised investors that Yutrepia does

not pose a competitive threat to the company. As late as this month, its management is reported to have predicted that Liquidia "is not a commercial threat due to undifferentiation across the board." (Doc. 34-23 at 1.) Contrary to UTC's expert's predictions that Yutrepia's entry would generally erode UTC's market share, UTC is reported to have told investors this May that it expects to lose only 5% market share to Liquidia. (Doc. 34-23 at 1.) UTC's president advised investors that it expects "to continue to grow revenues at double-digit growth . . . this year and next year." (Doc. 34-22 at 9.) And in March 2023, its chairman stated that if Liquidia is approved, it "does not challenge our projected double-digit growth." (Doc. 34-28 at 4.) According to UTC's founder, chairman and CEO, this is because Yutrepia is "not a generic product, but is instead a strongly differentiated drug device product requiring 65% more drug to even match Tyvaso's effect based on their own clinical trial data." (Id.) These public statements should be deemed credible because they are made to investors and the market.

The court accepts that UTC may lose sales to Yutrepia, but lost sales are in large part redressable by a damages award. While the availability of a conceivable damages award does not defeat UTC's ability to demonstrate irreparable harm, Celsis, 664 F.3d at 930 (citing Abbott Lab'ys., 544 F.3d at 1361–62), the fact that some asserted injuries are purely economic weighs against a finding

that UTC will suffer harm that is redressable only by injunctive relief.

This leaves UTC's argument that Liquidia is not financially capable of paying a damages award. UTC's expert, Dr. Selck, focuses on Liquidia's present financial condition and current revenue. (Doc. 5 ¶¶ 153–58.) In short, Liquidia is operating at a loss: -$121.3 million in 2024. (Id. ¶ 156.) While its ability to pay any significant damages award appears doubtful in the long term, as of December 2024, Liquidia reported $176 million in cash reserves. (Doc. 37 ¶ 126.) Of course, if the court does not restrain Yutrepia from sale, Liquidia would generate revenues from sales. Dr. Selck asserts that "[t]he profits that Liquidia makes from sales of Yutrepia are unlikely to be sufficient to compensate for the significant harm that [UTC] will suffer in the absence of an injunction." (Id. ¶ 157.) This opinion does not seem to account for the fact that the '782 patent, even if valid, would entitle UTC to exclusivity only until it expires on May 14, 2027. (Doc. 34-37 at 2.) Moreover, the public comments of UTC and its management that Liquidia is "not a commercial threat" and "does not challenge [UTC's] projected double-digit growth" suggests that any harm UTC may suffer will not be so "significant" that it is incapable of being addressed by a damages award. (Docs. 34-23 at 1; 34-28 at 4.)

Having found that UTC's claims of loss are overstated,

particularly in light of the very large segment of the unserved patient population, the court is not persuaded that UTC has demonstrated that Liquidia would be unable to pay a proportionate damages award if UTC ultimately proves infringement. This factor does not weigh in favor of granting relief at this time.[15]

C. Balance of the Equities

To assess the balance of the equities, the court weighs the harm to the moving party if injunctive relief is not granted against the harm to the non-moving party if the injunction is granted. Metalcraft of Mayville, Inc. v. Toro Co., 848 F.3d 1358, 1369 (Fed. Cir. 2017).

UTC asserts that it "will suffer severe and irreversible harm that outweighs any potential hardship to Liquidia from maintaining the status quo for a few short weeks." (Doc. 4 at 31.) It emphasizes that it "has undertaken significant and costly efforts to research, develop, patent, and commercialize Tyvaso products and develop the relevant market, and its billions-of-dollars spent on research and development from 2017-2022 outstrips Liquidia's by at least an order of magnitude." (Id. (citing Doc. 5 ¶¶ 161-68).) Liquidia's harms, in contrast, would be minimal, it argues, because Yutrepia has not launched yet, and Liquidia "made the conscious decision to piggyback on UTC['s] efforts" rather than conduct its

[15] The court therefore need not address Liquidia's nexus argument.

own research, development, and clinical trials. (Id. at 32.)

Liquidia argues that its status as a "new market entrant" compared to UTC's position as a "well-capitalized company" which "has enjoyed nearly twenty years of market dominance and $2.33 billion in yearly revenue" tips the balance of the equities in its favor. (Doc. 34 at 23.) It also points out that the District Court in Delaware concluded that the balance did not favor either party and urges this court to reach the same conclusion. (Id.)

The court concludes that the competing equities favor neither party. On the one hand, denying an injunction would permit Liquidia to enter the market and sell Yutrepia before the validity of the '782 patent is conclusively determined, potentially harming UTC. Yet, as noted above, UTC's own management has predicted as late as this month that Liquidia "is not a commercial threat due to undifferentiation across the board" and that, consistent with that, the company's price and sales projections chart continued growth. (Docs. 34-22 at 9; 34-23 at 1; 34-28 at 4.) Therefore, UTC's claims of harm are diminished by these public statements, which the court deems credible. On the other hand, Liquidia has raised a substantial question as to the validity of the '782 patent, and prohibiting Liquidia from moving forward would raise an additional barrier at the eleventh hour for a treatment that has received final FDA approval. As a smaller company that is running substantial losses pending market launch, Liquidia stands

to lose significantly if its flagship product is restrained from the market indefinitely. Continued delay, after years of (to this point at least) successful litigation against UTC, will be costly to it.

D. The Public Interest

The final factor that the court must consider is the public interest. UTC observes that "[t]he public interest nearly always weighs in favor of protecting property rights." (Doc. 4 at 33 (internal quotation mark omitted) (quoting Apple Inc. v. Samsung Elecs. Co., 809 F.3d 633, 647 (Fed. Cir. 2015)).) Moreover, UTC argues, "[t]he compelling public interest in encouraging investment and innovation in drug development outweighs 'a general interest in access to lower-cost drug products' via an infringing, cheaper alternative." (Id. (quoting In re Aflibercept Pat. Litig., No. 1:24-MD-3103, 2024 WL 3422971, at *49 (N.D.W. Va. June 24, 2024)).) Lastly, UTC represents that it has "ample capacity to meet the demands of the market" for PAH and PH-ILD treatments with its Tyvaso and Tyvaso DPI products, so the issuance of injunctive relief would not leave any patients "without the medicine they need." (Id. at 33.)

Liquidia counters that the court should instead focus on "the tens of thousands of patients suffering from PAH and PH-ILD" that stand to benefit from the introduction of Yutrepia to the market. (Doc. 34 at 23.) It also disputes that UTC has the capacity to

meet the market demand on its own. (Id. at 23–24.) And it contends that the Delaware District Court's conclusion that the public interest would suffer if equitable relief prohibited Liquidia from launching Yutrepia has even more force here because UTC seeks to block Yutrepia for "all indications" in the present suit but only sought to block its use for PH-ILD patients in the Delaware case. (Id. at 24.)

UTC is correct that there is a substantial public interest in protecting the intellectual property rights of inventors, and that such interest does not give way to a general interest in a lower-cost, infringing drug alternative. But that public interest loses force where, as here, the inventor's claim to a valid intellectual property right is subject to serious question. See Abbott Lab'ys. v. Andrx Pharms., Inc., 452 F.3d 1331, 1348 (Fed. Cir. 2006) (concluding that because "as a substantial question of patent validity has been raised by [defendant], the public interest benefits from a denial of the injunction").[16] Liquidia persuasively argues that PH patients benefit from having treatment options because "different therapies work better for different patients." (Docs. 34 at 24; 34-29.) And as noted, even under

[16] Even the decision UTC cites recognizes that the public interest calculus changes where a party "seek[s] to enjoin the sale of lifesaving drugs." Apple Inc. v. Samsung Elecs. Co., Ltd., 809 F.3d 633, 647 (Fed. Cir. 2015). Both parties acknowledge that PH is a serious, often fatal disease and their treatments can change, if not save, PH patients' lives. (Docs. 4 at 10–12 ("life-changing"); 34 at 10 ("life-saving").)

UTC's own projections, UTC treats a fraction of the growing population of PH and PH-ILD patients, and it does not anticipate treating even half of the PH-ILD patients until 2030. Thus, UTC does not currently meet market need and likely will not for years, if ever. UTC attributes this in part to a need to educate doctors (Doc. 43 at 32–33.) Even so, it shows excess market capacity that remains unserved.

In light of the court's substantial question regarding the validity of the '782 patent, the evidence strongly suggesting that PH and PH-ILD patients are likely to benefit from the use of Yutrepia, and the fact that UTC does not currently meet the patient need for PH and PH-ILD treatment and would not likely do so in the near future if an injunction were entered, the court concludes that the public interest favors Liquidia and the denial of injunctive relief.

III. CONCLUSION

For the reasons stated,

IT IS THEREFORE ORDERED that Plaintiff's Motion for a Temporary Restraining Order and Preliminary Injunction (Doc. 3) is DENIED.

/s/ Thomas D. Schroeder
United States District Judge

May 30, 2025